II. Remarks

A. Status of the Claims

Claims 13-24 and 57 are currently pending. Claims 1-12 and 25-56 were previously cancelled. Claim 1 has been amended. Claim 18, 19 and 22 have been withdraw from consideration.

The Applicants acknowledge with appreciation the Examiner's indication that the rejections under 35 U.S.C. § 112 and 35 U.S.C. § 103(a) from the previous Office Action have been overcome.

B. New Claim Rejections Under 35 U.S.C. § 103(a)

1. Sunshine et al. in view of Vishwanathan et al.

In the Office Action, claims 13-16, 20, 21, 23, 24 and 57 were rejected under 35 U.S.C. § 103(a) on the grounds of being unpatentable over U.S. Patent No. 4,780,463 (Sunshine et al.) in view of U.S. Publication No. 2002/0119192 (Vishwanathan et al.). The Examiner stated that "[i]t would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a dosage form containing both immediate and sustained release baclofen, as taught by Sunshine et al., and to use the controlled release polymers taught as suitable for the controlled release of baclofen, taught by Vishwanathan et al. to prepare the controlled release portion of the dosage form."

This rejection is respectfully traversed. In the Office Action, the Examiner acknowledged that Sunshine et al. do not disclose "specific controlled release polymers" (page 4 of the Office Action) and relies upon Vishwanathan et al. for allegedly teaching suitable polymers to provide a controlled release of baclofen.

The Examiner alleges that Vishwanathan et al. discloses that "[t]he inclusion of the hydroxyalkyl cellulose polymer hydroxypropyl methyl cellulose extends the release profile to about 10 hours (paragraph [0022])" and that "[o]ther polymers suitable for inclusion ... include acrylic polymers such as those available under the EUDRAGIT

trade name (paragraph [0038]) and a variety of cellulose ethers, including several hydroxyalkyl cellulose polymers and alkyl cellulose polymers (paragraph [0040])."

In making these statements, however, the Examiner fails to recognize that the inclusion of cellulosic and acrylic polymers in the Vishwanathan et al. compositions are in addition to carboxyvinyl polymer which is a necessary and mandatory component of the compositions described therein. Applicants note that carboxyvinyl polymer is excluded by the current claims by virtue of the "consisting essentially of" terminology and the Markush listing of possible controlled release materials in the present claims.

In support of the position that carboxyvinyl polymer is a necessary and mandatory component of the compositions of Vishwanathan et al., and that cellulosic and acrylic polymers described therein are optional secondary ingredients, the Examiner is directed to the following paragraphs in the reference:

> "[0014] It is an object of the present invention to provide an oral controlled drug delivery system of drug which:
> [0015] a. comprises carboxyvinyl polymer that gelatinizes in the alkaline environment and regulates the release of drug;
> [0016] b. comprises hydrophilic polymers that swell upon imbibition of water and further provides for controlled release of drug..." (Emphasis added)
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> ***
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> "[0021] More particularly, the present invention describes a pharmaceutical composition for oral administration in humans for the controlled release of a therapeutic agent comprising an effective amount of drug in combination with a polymeric matrix characterized in that at least one such polymer is carboxyvinyl polymer and which constitutes at least 30% by weight of the total polymeric content, an alkaline compound and optionally, other pharmaceutically acceptable auxiliary components.
> [0022] It has also been discovered that cellulose ethers, preferably, hydroxypropyl methylcellulose, when added to the pharmaceutical compositions extends the in-vitro drug release profile to about 10 hours which forms another aspect of the present invention. Further, compositions

> including cellulose ethers exhibit a drug release profile that is better controlled and sustained." (Emphasis added)"
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> ***
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> "[0038] According to the present invention, the polymeric matrix comprises carboxyvinyl polymer in conjunction with other hydrophilic polymers which together regulate the release of drug. (Emphasis added)"
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> ***
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> "[0040] According to the present invention the polymeric matrix comprises carboxyvinyl polymer and additionally, cellulose ethers in conjunction with other hydrophilic polymers which together regulate the release of drug suitable for once-a-day dosage regimen. (Emphasis added)"

As described in the above paragraphs, carboxyvinyl polymer is a necessary ingredient in the Vishwanathan et al. formulations. The cellulosic and acrylic polymers described therein are optional secondary ingredients that may be included in addition to the carboxyvinyl polymer.

This is further evidenced by examples 1-6 of Vishwanathan, all of which necessarily include carboxyvinyl polymer as an ingredient. See, e.g., Example 1, Table 1; Example 2, Table 4; Example 3, Table 6; Example 4, Table 8; Example 5, Table 10; Example 6, Table 12.

Therefore, relying upon Vishwanathan et al., one skilled in the art would necessarily include carboxyvinyl polymer as a controlled release polymer for a baclofen formulation.

The present claims exclude carboxyvinyl polymer as a possible controlled release material by virtue of the "consisting essentially of" terminology and the recited Markush limitation that the controlled release material is "selected from the group consisting of an acrylic polymer, an alkylcellulose, shellac, zein, hydrogenated castor oil, hydrogenated vegetable oil, a hydroxyalkylcellulose, and a combination thereof". Applicants

respectfully submit that carboxyvinyl polymer does not fall within any of the recited controlled release materials.

Further, as Vishwanathan et al. discloses that carboxyvinyl polymer is a necessary ingredient in the formulations therein, one skilled in the art would be taught away from preparing the presently claimed baclofen formulation which necessarily does not include carboxyvinyl polymer.

Accordingly, Applicants respectfully submit that the rejection under 35 U.S.C. § 103(a) over Sunshine et al. in view of Vishwanathan et al. be withdrawn.

2. Sunshine et al. in view of Vishwanathan et al. further in view of Fara et al.

In the Office Action, claims 13 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sunshine et al. in view of Vishwanathan et al. as applied above, further in view of U.S. Patent application No. 2003/0031711 (Fara et al.).

Fara et al. is relied upon solely for teaching racemic baclofen and does not cure the deficiencies of Sunshine et al. in view of Vishwanathan et al. as discussed above.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Sunshine et al. in view of Vishwanathan further in view of Fara et al. be removed.

3. Sunshine et al. in view of Vishwanathan et al. further in view of Patel et al.

In the Office Action, claims 13, 23 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sunshine et al. in view of Vishwanathan et al. as applied above, further in view of Patel et al.

Fara et al. is relied upon solely for teaching capsules comprising discreet units and does not cure the deficiencies of Sunshine et al. in view of Vishwanathan et al. as discussed above.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Sunshine et al. in view of Vishwanathan further in view of Patel et al. be removed.

III. Conclusion

In view of the amendments made and arguments presented, it is believed that all claims are in condition for allowance. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is invited to telephone the undersigned at (973)597-2404. The undersigned also may be contacted via e-mail at rparadiso@lowenstein.com. All correspondence should be directed to our address listed below.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account No. 50-1358.

Respectfully submitted,
Lowenstein Sandler PC

Date: July 29, 2008

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